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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,773	06/05/2002	Frank Volke	31583-178427 RK	3754
26694	7590	04/14/2004	EXAMINER	
VENABLE, BAETJER, HOWARD AND CIVILETTI, LLP P.O. BOX 34385 WASHINGTON, DC 20043-9998			METZMAIER, DANIEL S	
			ART UNIT	PAPER NUMBER

1712

DATE MAILED: 04/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/069,773	Applicant(s) VOLKE ET AL. 	
	Examiner Daniel S. Metzmaier	Art Unit 1712	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 6-12 is/are pending in the application.
- 4a) Of the above claim(s) 6-8 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10-12 is/are allowed.
- 6) ☒ Claim(s) 9 is/are rejected.
- 7) ☒ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

### **DETAILED ACTION**

Claims 6-12 are pending. Claims 1-5 have been canceled.

#### ***Election/Restrictions***

1. Newly submitted claims 6-8 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 6-8 require the combination of a coupling medium with a probe, which defines an apparatus not set forth in the original claims.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 6-8 have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

#### ***Claim Objections***

2. Claim 10 is objected to because of the following informalities: "polysaccharideor" is misspelled. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Haefele, US 3,427,382. Haefele (examples) discloses gel compositions, which read on the claimed

Art Unit: 1712

compositions and would have been expected to function as an ultrasound coupling medium since the compositions otherwise read on the claimed compositions. Haefele (column 5, lines 15-18) discloses the thickening agents reduces the acute oral toxicity of the gels. The disclosed compositions are biocompatible as skin/hair compositions.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buchalter, US 4,002,221, in view of Larson et al, US 6,039,694. Buchalter (abstract, examples and claims) discloses gelled coupling agents for ultrasonic impulses. Hydroxyethylcellulose is a polysaccharide.

Buchalter differs from the claims in the further addition of a surfactant and the characterization that the medium is for transverse waves.

Larson et al (item [56] on patent face and column 2, lines 40-46) cites Buchalter, 4,002,221, and characterizes fluids or thickened water-based gels typically used in medical ultrasound similarly described in Buchalter to include cellulose ethers and other germicidal and fungicidal, and surfactants.

These references are combinable because they teach ultrasound coupling agents. It would have been obvious to one of ordinary skilled in the art at the time of applicants' invention to employ a surfactants as an obvious conventional additive for medical ultrasound coupling mediums as taught and evidenced in the Larson et al reference.

The prior art and the instant application do not show any difference in the transmission of transverse waves and longitudinal waves in the coupling medium. The skilled artisan would have reasonably expected the medium to transmit either wave energy if it is taught as a coupling medium.

The instant specification does not provide comparative examples or evidence in the prior art, which would provide unexpected results of the claimed coupling medium.

***Allowable Subject Matter***

8. Claims 10-12 are allowed.
9. The following is a statement of reasons for the indication of allowable subject matter: the methods set forth in claims 10-12 transmitting transverse ultrasonic waves

Art Unit: 1712

and employing a coupling compositions as claimed. Said coupling compositions are further characterized at page 6, second paragraph, of the instant specification.

***Response to Arguments***

10. Applicant's arguments filed December 31, 2004 have been fully considered but they are not persuasive.

11. Applicants (page 5) assert that all the elements have not been taught in Haefele. The Office Action directs attention to the Haefele examples. The claim requires a homogenized mixture of a polysaccharide, a surface-active agent and water. Haefele (example 1) sets forth a gel comprising Methocel 60-HG (cellulose derivative) is a polysaccharide as claimed. See claim interpretation in the last office action, which is incorporated herein by reference. The cetyl dimethyl benzyl quaternary ammonium chloride is surface active and the composition has a balance of water, which is about 38 % by weight. The disclosed compositions are biocompatible as skin/hair compositions. The properties as a coupling medium would have been inherent to the Haefele compositions.

12. Applicants (pages 6 and 7) assert the properties of coupling agents required for longitudinal and traverse ultrasonic waves and direct attention to paragraph three of page one of the instant specification. Said citation indicates a requirement for shear stability but lacks any quantification of said stability. Said citation further states water is unsuitable. Water as cited is not comparable to the compositions cited in the prior art of record.

Applicants do not provide evidence on which they base their conclusions. Attorney's arguments cannot take the place of evidence in the record. In re DeBlauwe, 736 F.2d 699, 705, 222 U.S.P.Q. 191, 196 (Fed. Cir. 1984).

***Conclusion***

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Crotty et al, US 3,655,579, is cited as cumulative to Haefele for claims 3 and 5.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel S. Metzmaier whose telephone number is (703) 308-0451. The examiner can normally be reached on 9:00 AM to 5:30 PM.

Art Unit: 1712

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on (571) 272-1119. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**Daniel S. Metzmaier**  
**Primary Examiner**  
**Art Unit 1712**

DSM